

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Notice of Electronic Prescription Files

Sections Affected: Repeal 1717.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes repealing section 1717.2 of Division 17 of Title 16 of the California Code of Regulations. The purpose for repealing the regulation is to remove a now-outdated barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy because of other federal and state laws. Additionally, there is now federal and state legislation in place to better protect a consumer's medical information without compromising a consumer's safety.

Factual Basis/Rationale

Section 1717.2, adopted in 1986, requires pharmacies that use and share electronic files with other pharmacies, to notify their customers that the customer can choose not to have their files shared with other pharmacies.

Both state and federal laws protect the confidentiality of patients' electronic medication records. Section 1717.2 was adopted before state and federal laws were enacted to address this issue. This section is now obsolete and conflicts with Health and Safety Code section 11165.

In 1996, the federal government enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to improve the efficiency and effectiveness of the health care system. HIPAA included provisions designed to encourage electronic transactions while protecting the security and confidentiality of health information. In December 2000, the Department of Health and Human Services (HHS) published a final regulation in the form of privacy rules in response to the HIPAA mandate. This Privacy Rule set national standards for the protection of health information, as applied to three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. The rule established for the first time a foundation of federal protections for the privacy of protected health information and the imposition of substantial civil or criminal penalties against those entities that failed to comply with the implementation date. The HIPAA Privacy Rule gives individuals a

fundamental right to be informed of the privacy practices of their health plan and of most of their health care providers, as well as to be informed of their privacy rights with respect to their personal health information.

In 2000 California enacted the Confidentiality of Medical Information Act, Civil Code 56.10.

This act states that no provider of health care, health care service plan or contractor can disclose medication information regarding a patient or the provider without first obtaining an authorization. While this act does provide for some exceptions, the act is explicit when these exceptions can occur and provides several safeguards for consumers to ensure the protection of their medical records.

In addition to these subsequent pieces of legislation, existing Section 1717.2 is in conflict with the Medi-Care Part D requirements as detailed in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Specifically, the Medi-Care Part D program requires mandatory coordination of a patient's pharmacy records to ensure coverage under the plan. Because of program nuances, a patient's coverage may not be applicable during a period referred to as the "doughnut hole." If patients' are allowed to elect out of the electronic system, it renders the benefits of the Medi-Care Part D program totally ineffective because a patient's pharmacy services cannot be confirmed. In this scenario, it is the consumer who loses out on additional benefits and coverage they may be entitled to should they have chosen not to elect out of a computer system.

Section 1717.2 also impedes a pharmacist's ability to complete a thorough drug utilization review of a patient's drug history, because certain medication information may not be available to the pharmacist to review. This could result in consumer harm and or death because of drug allergies and or serious drug interactions. Specifically, prior to dispensing a new prescription, a pharmacist reviews a patient's drug history, drug allergies and current medications. This information is only available if it is contained within the pharmacy's computer system and can be shared. If a patient opts out of the computer system, it negates the drug utilization review which can be a life saving measure. Repealing Section 1717.2 can reduce adverse drug reactions and even save lives. Moreover, existing board regulation Section 1775.1(b) allows the board to cite and fine a pharmacy or pharmacist as specified in Section 56.36 of the Civil Code for failure to maintain the confidentiality of a patient's medications and health care. Specifically, Section 56.36 states that any licensed health care professional, who knowingly and willfully obtains, discloses or used medication information in violation of this act for financial gain shall be subject to an administrative of \$5,000 per violation, up to \$250,000 for subsequent violations.

Health and Safety Code section 11165 provides for the electronic monitoring of prescribing and dispensing of Schedule II and III controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program. (Currently pending California legislation could extend this to also include Schedule IV drugs.) This law states that for each prescription for a Schedule II or III controlled substance, the dispensing pharmacy must provide information to the Department of Justice (DOJ),

including the name, address, gender and date of birth of the patient, the National Drug Code (NDC) number of the controlled substance dispensed as well as the quantity dispensed, issue date of the prescription and dispensing date of the prescriptions. There are no exceptions to this reporting requirement. As such, the pharmacy must maintain this information and provide it to the DOJ, even if the patient directs that the information not be shared.

With today's substantial laws in place to protect consumers' medical record information, it seems appropriate for the board to review the usefulness of Section 1717.2.

For all of the reasons cited above the board is pursuing the repeal of Section 1717.2 of the California Code of Regulations.

Underlying Data

California Civil Code 56.10

Health and Safety Code section 11165

45 Code of Federal Regulations Parts 160 and 164

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to repealing the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the repeal of the regulation.